

UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

UNITED STATES OF AMERICA,

v.

JERROLD ROSENBERG,

Defendant.

FILED

FEB 1 2017

U.S. DISTRICT COURT
DISTRICT OF RHODE ISLAND

Criminal No. 17 09 M

In Violation of:

Counts 1-13: 18 U.S.C. § 1347
(Health Care Fraud)

Count 14: 18 U.S.C. § 371
(Conspiracy to Pay and Receive
Kickbacks)

Counts 15 - 19: 42 U.S.C. § 1320a-
7b(b) (Receipt of Kickbacks)

INDICTMENT

The Grand Jury charges that:

Introduction

The Defendant, His Medical Practice and Office Staff

At all times material and relevant to this Indictment, unless otherwise set forth herein:

1. Jerrold Rosenberg ("ROSENBERG") was a physician licensed to practice medicine in the State of Rhode Island. ROSENBERG specialized in physiatry, also called physical medicine and rehabilitation, a branch of medicine that specializes in the diagnosis and treatment of pain as a result of injury, illness or a disabling condition.

2. From in or about February 1995 through March 2015, ROSENBERG's medical office was located at 827 North Main Street, Providence, Rhode Island. In or about 2015, ROSENBERG moved his medical practice to 1637 Mineral Spring Avenue, North Providence, Rhode Island, where it currently remains.

3. R. S.D. was a licensed Physician's Assistant in the State of Rhode Island. From in or about February 2013 through March 2014, R. S.D. was employed by ROSENBERG and treated patients at ROSENBERG's medical practice.

4. J. S.P. was employed by ROSENBERG as a member of the office staff until in or about 2015. One of J. S.P.'s responsibilities was to assist in the process of securing prior authorization from patients' health insurance companies for drugs prescribed by ROSENBERG and R. S.D.

5. L.R. was employed by ROSENBERG as a member of the office staff. One of L.R.'s responsibilities was to assist in the process of securing prior authorization from patients' health insurance companies for drugs prescribed by ROSENBERG and R. S.D.

6. E.G. was employed by ROSENBERG as the office manager until in or about December 2014.

THE PHARMACEUTICAL COMPANY AND THE FENTANYL SPRAY

7. The "Pharmaceutical Company" is a company incorporated in Delaware and headquartered in Chandler, Arizona.

8. On or about January 4, 2012, the Food and Drug Administration ("FDA") approved the Pharmaceutical Company's application to market a drug (hereinafter "the Fentanyl Spray") to patients suffering from breakthrough cancer pain. Breakthrough cancer pain is severe pain that erupts in patients with cancer who are already medicated with a long-acting painkiller.

9. The Fentanyl Spray is a potent opioid containing fentanyl that is designed to rapidly enter a patient's bloodstream upon being sprayed under the tongue. Fentanyl is a synthetic opioid that is classified as a Schedule II controlled substance under the Controlled Substances Act. It is primarily utilized as a pain relief medication. Fentanyl produces effects that are practically indistinguishable from the opioids morphine and heroin, but fentanyl has a greater potency and a shorter duration of action. Fentanyl is rapidly distributed to the brain, heart, lungs, kidneys and spleen.

10. Drugs like the Fentanyl Spray which contain fentanyl are highly addictive and can lead to physical and/or psychological dependence, abuse and addiction.

11. Due to the potency of the drug and the potential for addiction, the FDA approved the use of the Fentanyl Spray solely for "the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are already tolerant to opioid therapy for their underlying persistent cancer pain."

12. Virtually all of the Pharmaceutical Company's profits came from the prescribing of the Fentanyl Spray by health care providers in the United States. In 2015, for example, the Pharmaceutical Company reported approximately \$330 million in net revenue from the Fentanyl Spray.

13. The Fentanyl Spray is approved for use in dosages of 100, 200, 400, 600, 800, 1200 or 1600 micrograms. Patients are to take one dose of the Fentanyl Spray per episode of breakthrough cancer pain and must wait four hours to take another dose of the Fentanyl Spray if experiencing breakthrough pain. Further, patients are instructed to limit the amount of the Fentanyl Spray they take to four or fewer doses per day.

14. As a fentanyl product, the Fentanyl Spray has a high risk of misuse, abuse, addiction and overdose. To reduce these risks, on December 28, 2011, the FDA approved a single, shared system Risk Evaluation and Mitigation Strategy (REMS) for the entire class of transmucosal immediate-release fentanyl (TIRF) prescription medicines. This "TIRF REMS" Access program, consists of a restricted distribution program. Accordingly, in each instance in which a patient is prescribed the Fentanyl Spray, both the prescriber and the patient must complete and submit a Patient-Prescriber Agreement Form detailing the risks and obligations imposed on both parties when a fentanyl product is prescribed.

15. Before prescribing a TIRF drug like the Fentanyl Spray to a patient, the prescriber must complete and sign a REMS form which explicitly states, "I understand that TIRF medications are indicated only for the management of breakthrough pain in patients with cancer who are already receiving, and who are tolerant to, around-the-clock opioid therapy for their underlying persistent pain."

16. The Fentanyl Spray is exceptionally expensive. The approximate retail cost of the Fentanyl Spray ranges from just under \$2,000 per month for 30 doses of the Fentanyl Spray at 200mcg to over \$8,000 per month for 30 doses of the Fentanyl Spray at 1600 mcg. The cost of the Fentanyl Spray can exceed \$16,000 per month if multiple doses per day are prescribed.

17. M.B. was the Chief Executive Officer and President of the Pharmaceutical Company from 2009 until on or about November 5, 2015.

18. A.B. held senior management positions, including Vice President for Sales, at the Pharmaceutical Company, from September 2013 until 2015.

19. J.P. was employed by the Pharmaceutical Company from approximately September 2012 until December 2015. J.P. was first hired by the Pharmaceutical Company as a sales representative and in February 2013 was promoted to the position of District Sales Manager. In this position, J.P. was responsible for managing the Pharmaceutical Company's sales representatives in Rhode Island and other northeastern states.

20. J.R. was hired by the Pharmaceutical Company in approximately March 2013 as a sales representative in the New York City area. In or about October 2013, J.R. was promoted to the position of District Sales Manager for the territory that included Rhode Island.

21. A.R. is the son of defendant JERROLD ROSENBERG. From June 2012 – September 2013, A.R. was employed at the Pharmaceutical Company as a sales representative in Rhode Island and neighboring states. In this position, A.R. was responsible for increasing the number of doctors in his region prescribing the Fentanyl Spray and encouraging doctors who were already prescribing the Fentanyl Spray to prescribe it to more patients and at higher doses. A large portion of A.R.'s compensation was commission-based and the majority of A.R.'s compensation stemmed from his father, JERROLD ROSENBERG, prescribing the Fentanyl Spray to his patients.

22. N.L. was employed as a sales representative for the Pharmaceutical Company in the New York region, including Rhode Island, from approximately March 2013 to August 2014. The majority of N.L.'s compensation was based on commissions and she received substantial commissions based on ROSENBERG's prescribing of the Fentanyl Spray to his patients.

23. J.C. was employed as an assistant business liaison and a sales representative for the Pharmaceutical Company in the New York region, including Rhode Island, from February 2014 to November 2015. The majority of J.C.'s compensation was based on commissions.

The Medicare Program and The Fentanyl Spray

24. The Medicare Program was established in 1965 pursuant to amendments to the Social Security Act. The Medicare Program is a health care benefit program that provides basic health insurance coverage to certain disabled persons as well as to individuals 65 years or older. Eligible persons can elect to participate in the program by completing an application and either agreeing to pay a premium for Medicare benefits, or arranging for a third party to pay such premiums. Persons enrolled in the Medicare programs are hereinafter referred to as "beneficiaries."

25. The Medicare program also includes a prescription drug program known as "Part D," which is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. The Part D program is administered by many "Plan Sponsors," each of which dictates the specific drugs it will cover and how much it will pay for those medications. The Centers for Medicare and Medicaid Services ("CMS"), through the federal treasury, reimburses the Part D Plan Sponsors for the covered drugs. Medicare is a "federal health care program" under 42 U.S.C. § 1320a-7b(b)(f) and a "health care benefit program" under 18 U.S.C. § 1347.

26. The United States Department of Health and Human Services, via CMS, contracts with various Plan Sponsors to provide prescription drug benefits to Medicare eligible beneficiaries. In Rhode Island, there are numerous Plan Sponsors that cover state residents. UnitedHealth Care, Silverscript Insurance Company, Humana, First Health Life and Health Insurance Company, Health Net, Blue Cross Blue Shield of Rhode Island and Wellcare Prescription Insurance are each Medicare Plan Sponsors that cover Rhode Island residents.

27. Each of these Medicare Plan Sponsors will only approve payment for the Fentanyl Spray that is prescribed to a Medicare patient if certain criteria are met, including (i) that the patient have a diagnosis of cancer, (ii) that the use of the Fentanyl Spray is for breakthrough cancer pain, and (iii) that other strong-acting narcotic pain relievers have been tried and been ineffective, not tolerated or contraindicated.

28. The Plan Sponsors contract with Pharmacy Benefit Managers ("PBMs"), which handle the administration of the prescription drug benefit on behalf of the Medicare Part D Plan Sponsors. Plan Sponsors contract with PBMs in order to provide its enrollees with access to a multi-tiered drug formulary and pharmacies which can dispense medication that is covered by the Plan Sponsors.

29. OptumRX, Catamaran, CVS Caremark, United Healthcare and Humana Pharmacy Solutions are all PBMs that have contracted with Plan Sponsors to administer the prescription drug benefit for Medicare beneficiaries residing in Rhode Island.

30. When a prescription for the Fentanyl Spray is filled by a pharmacy, the PBM with which the pharmacy contracts sends a “claim” to the Plan Sponsor for payment. This payment is based upon the agreed upon rates set between the PBM and the drug’s manufacturer; CMS does not negotiate the costs for drugs covered under Part D. The Plan Sponsor pays the claim to the pharmacy and provides CMS with a Prescription Drug Event (“PDE”), which allows the Plan Sponsor and CMS to reconcile the amount spent for dispensed medication at the end of each year. CMS pays Plan Sponsors a lump sum at the start of the fiscal year and then adjusts this payment upon reconciliation.

Private Insurance Companies and The Fentanyl Spray

31. Blue Cross-Blue Shield, United Healthcare and Neighborhood Health Plan of Rhode Island are each private “health care benefit programs” under 18 U.S.C. § 1347 that provide health insurance benefits to its members in exchange for the payment of premiums. These private insurance companies only approve payment for the Fentanyl Spray that is prescribed to a plan member if certain criteria are met, including (i) that the patient have a diagnosis of cancer, (ii) that the use of the Fentanyl Spray is for breakthrough cancer pain, and (iii) that other strong-acting narcotic pain relievers have been tried and been ineffective, not tolerated or contraindicated.

Prior Authorization Procedure

32. Medical facilities, practitioners, insurers, PBMs, government entities and pharmacies employ a set of codes to classify diseases and injuries. The codes, which are recognized around the world, are called the International Statistical Classification of Disease and Related Health Problems 9th Revision ("ICD-9"). There is a recognized ICD-9 code for each medical diagnosis. Insurers and practitioners used ICD-9 codes when communicating about prior authorizations.

33. Because of the high cost of the Fentanyl Spray, all of the Medicare Plan Sponsors and private insurance companies require providers to obtain authorization prior to the filling of a Fentanyl Spray prescription. Providers are typically required to prepare and complete written Prior Authorization requests in which information concerning the patient and his or her diagnosis, including the ICD-9 code, is provided. On the Prior Authorization form, the provider must also confirm whether the patient has an active diagnosis of cancer, whether the use of the Fentanyl Spray is for breakthrough cancer pain, whether the patient is opioid tolerant and whether other short-acting narcotics have been tried and proven ineffective. Upon receipt of a completed Prior Authorization form, the Plan Sponsor, PBM or private insurance company makes a determination as to whether it will approve payment for the Fentanyl Spray prescription.

34. Some PBMs accept a phone call from the provider with a verbal request for prior authorization of the Fentanyl Spray. During these verbal requests, the provider is asked whether the patient has an active diagnosis of cancer, whether the use of the Fentanyl Spray is for breakthrough cancer pain, whether the patient is opioid tolerant and whether other short-acting narcotics have been tried and proven ineffective.

35. In the event that a Medicare Plan Sponsor, PBM or private insurance company denies the Prior Authorization request, a notice of such determination is sent to the patient and provider. The provider can appeal this denial and submit a letter to the insurance company, called a "Letter of Medical Necessity," asking it to reconsider its denial of coverage for the Fentanyl Spray. In this Letter of Medical Necessity, the provider typically describes the patient's medical condition in greater detail and explains why, in the provider's view, the drug should be approved for the patient.

The Pharmaceutical Company Reimbursement Center

36. In or about January 2013, due to the difficulty doctors were having in obtaining approval for the Fentanyl Spray from insurance companies, the Pharmaceutical Company established a group known as the "IRC." The IRC was comprised of a group of Pharmaceutical Company employees based in Arizona who specialized in obtaining approval from insurance companies for payment for the Fentanyl Spray.

37. If a provider elected to use the services of the IRC for a particular patient to whom he/she prescribed the Fentanyl Spray, the provider would complete a

“Reimbursement/Prior Authorization Request” form and fax a copy of that request to the IRC. On this form, the provider would provide confidential patient information such as the name, date of birth, insurer information, the medical diagnosis or diagnoses for which the Fentanyl Spray was being prescribed, and the corresponding ICD-9 code associated with each diagnosis. The IRC would then use the information provided and initiate the prior authorization process with the insurance company.

The Pharmaceutical Company Speaker Programs

38. In 2012, the Pharmaceutical Company established a program, called the “ISP,” in which doctors and other providers would be compensated for providing educational programs concerning the Fentanyl Spray to other health care providers. The officially stated purpose of this program was to gather licensed health care professionals who had capacity to prescribe this fentanyl spray and educate them about the drug.

39. Many of the ISP programs took place at high-end restaurants, at which the presenter would purportedly speak about the benefits of the Fentanyl Spray. The Pharmaceutical Company paid for the cost of the meal, up to \$125 per person. In addition, the Pharmaceutical Company paid the speaker a flat fee, ranging from \$1,000 to several thousand dollars per session.

40. In or about June 2012, ROSENBERG was approved by the Pharmaceutical Company to become a speaker for the Fentanyl Spray. From July 2012 - July 2015, ROSENBERG was a very active speaker for the Fentanyl Spray, purportedly giving approximately 91 presentations at various restaurants and doctor's offices. For each of these purported presentations, ROSENBERG was paid a fee of between \$1500 and \$2200. In total, ROSENBERG received approximately \$180,000 from the Pharmaceutical Company in compensation for purportedly speaking about the Fentanyl Spray.

41. At various times from 2012-2015, the Pharmaceutical Company hired third party companies Scimedica, Inc. ("Scimedica") and Plan 365, Inc. ("Plan 365") to manage the Speaker Program. In exchange for a fee, these companies made arrangements with the various restaurants where the presentations were held and made payments to the restaurants and the speakers. The sales representative assigned to the region was required to attend each speaking program and was required to submit a receipt, sign-in sheet and evaluation form for each program.

COUNTS 1 - 13
(Health Care Fraud)

42. The Grand Jury realleges and incorporates by reference paragraphs 1-41 above as if fully set forth herein.

The Scheme

43. Beginning in or about April 2012, and continuing to in or about July 2015, in the District of Rhode Island, and elsewhere, the defendant, JERROLD ROSENBERG, knowingly and willfully executed and attempted to execute a scheme and artifice to defraud any health care benefit program, in connection with the delivery of or payment for health care benefits, items and services.

Manner and Means

44. It was part of the scheme that defendant JERROLD ROSENBERG prescribed the Fentanyl Spray to numerous patients who did not have cancer or breakthrough cancer pain.

45. It was a further part of the scheme that defendant JERROLD ROSENBERG submitted or caused to be submitted fraudulent Prior Authorization requests for the Fentanyl Spray to the Plan Sponsors, PBMs, Insurance Companies and Pharmaceutical Company in which he falsely represented that his patients had cancer and that they were suffering from breakthrough cancer pain. In truth and in fact, defendant JERROLD ROSENBERG knew full well that these patients did not have cancer and were not suffering from breakthrough cancer pain when he submitted the false Prior Authorization requests. Many of these patients never had any form of cancer. Others

had previously been diagnosed with cancer but had recovered, were in complete remission and were suffering from pain completely unrelated to their prior cancer diagnoses.

46. It was a further part of the scheme that defendant JERROLD ROSENBERG submitted or caused to be submitted fraudulent Prior Authorization requests for the Fentanyl Spray to the Plan Sponsors, PBMs, Insurance Companies and Pharmaceutical Company in which he falsely represented that other short-acting narcotics had been tried and proven ineffective.

47. It was a further part of the scheme that defendant JERROLD ROSENBERG falsely and fraudulently gave his patients cancer diagnoses in his patient medical records. Upon seeing these false and fraudulent cancer diagnoses, his office staff, including J. S.P. and L.R., provided the false cancer diagnoses to the Plan Sponsors, PBMs and Insurance Companies when seeking preauthorization for the Fentanyl Spray.

48. It was a further part of the scheme that defendant JERROLD ROSENBERG submitted to the Plan Sponsors, PBMs and Insurance Companies false and fraudulent Letters of Medical Necessity for the Fentanyl Spray, in which he fraudulently wrote that his patients were suffering from cancer, that they were experiencing breakthrough cancer pain and that other short-acting narcotics had been tried and proven ineffective.

49. It was a further part of the scheme that defendant JERROLD ROSENBERG refused patients' requests to switch from the Fentanyl Spray to another pain relief medication even when patients suffered debilitating side effects from the Fentanyl Spray or when they obtained little or no pain relief from the Fentanyl Spray.

50. It was a further part of the scheme that, based on defendant's false and fraudulent representations, the Plan Sponsors, PBMs and Insurance Companies approved the payment for the Fentanyl Spray for numerous of defendant Rosenberg's patients who were not suffering from breakthrough cancer pain, causing hundreds of thousands dollars in losses to Medicare and the Insurance Companies.

51. It was a further part of the scheme that defendant JERROLD ROSENBERG received approximately \$180,000 in purported "speaking" fees from the Pharmaceutical Company. Defendant JERROLD ROSENBERG knew and believed that the Pharmaceutical Company would provide him with more paid speaking programs if he were able to successfully prescribe a large amount of the Fentanyl Spray to his patients that would be paid for by Medicare and the Insurance Companies.

52. It was a further part of the scheme that A.R. received greater commissions and income as a result of his father, defendant JERROLD ROSENBERG, prescribing large quantities of the Fentanyl Spray to his patients.

Execution of the Scheme

53. On or about the dates set forth below, in the District of Rhode Island, and elsewhere, for the purpose of executing the aforementioned scheme and artifice, and attempting to do so, the defendant, JERROLD ROSENBERG, did knowingly submit to the below listed Plan Sponsor, PBM or Insurance Company, for the patients identified below, the false and fraudulent material set forth below:

Count	Date	Plan Sponsor/ Pharmacy Benefit Manager/Insurance Company	Patient	False Material
1	07/23/2012	Silver Script	P.F.	Diagnosis of pain due to basal cell carcinoma in Prior Authorization Request
2	11/21/2012	Health Net	J.P.	Diagnosis of breakthrough cancer pain/ ovarian cancer in Letter of Medical Necessity
3	12/10/2012	Catamaran	J.M.	Diagnosis of breakthrough cancer pain in Letter of Medical Necessity
4	12/19/2012	Humana	A.M.	Diagnosis of breakthrough cancer pain due to bone marrow cancer in Letter of Medical Necessity

5	12/19/2012	Optum	D.M.	Diagnosis of breast cancer in Letter of Medical Necessity
6	01/28/2013	United Health Care	R.M.	Diagnosis of breakthrough cancer pain in Letter of Medical Necessity
7	02/12/2013	First Health	T.M.	Diagnosis of cervical cancer in Prior Authorization Request
8	03/20/2013	Catamaran	S.D.	Diagnosis of cancer associated pain in Prior Authorization Request
9	03/27/2013	Optum	T.C.	Diagnosis of breakthrough cancer pain in Letter of Medical Necessity
10	05/21/2013	Silver Script	M.M.	Diagnosis of cancer associated pain in Prior Authorization Request
11	06/25/2013	BlueCross – BlueShield	J.D.	Diagnosis of lung cancer in Pharmaceutical Company Prior Authorization Request
12	06/26/2013	Catamaran	D.N.	Diagnosis of cancer associated pain in Prior Authorization Request

13	03/24/2014	Humana	R.S.	Diagnosis of lung cancer in Pharmaceutical Company Prior Authorization Request
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Each in violation of 18 U.S.C. § 1347.

COUNT 14
(Conspiracy to Pay and Receive Kickbacks)

54. The Grand Jury realleges and incorporates by reference paragraphs 1-53 above as if fully set forth herein.

The Conspiracy

55. From in or about April 2012 through in or about July 2015, in the District of Rhode Island and elsewhere, defendant JERROLD ROSENBERG, did knowingly and willfully conspire and agree with M.B., A.B., J.P., J.R., A.R., N.L., J.C. and other persons known and unknown to the Grand Jury, to commit an offense against the United States, to wit to knowingly and willfully offer, pay, solicit, and receive any remuneration, directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing and ordering, and arranging for the purchase and order of goods, services and items, that is prescriptions for the Fentanyl Spray, for which payment was made in whole or in part by a Federal health care program, namely Medicare, contrary to 42 U.S.C. § 1320a-7b(b).

Objective of the Conspiracy

56. The objective of the conspiracy was the unlawful payment to and receipt of kickbacks by defendant JERROLD ROSENBERG as an inducement and in exchange for his prescribing the Fentanyl Spray to his patients.

Manner and Means of the Conspiracy

57. Due to the limited number of patients in the United States suffering from breakthrough cancer pain, the Pharmaceutical Company, by and through its officers and managers, designed and implemented a strategy aimed at inducing health care providers to prescribe the Fentanyl Spray for pain that was caused by conditions other than cancer. A primary target group for Pharmaceutical Company officials was pain specialists, like defendant ROSENBERG, who were treating a large volume of patients who were experiencing pain from a variety of medical conditions.

58. In order to induce pain specialists and other providers to prescribe the Fentanyl Spray to patients who were not suffering from breakthrough cancer pain, the Pharmaceutical Company in 2012 created the Pharmaceutical Company Speaker Program. The Pharmaceutical Company officials publically claimed that the purpose of the Speaker Program was to educate other providers concerning the benefits of the Fentanyl Spray. In reality, the primary purpose of the Speaking Program was to provide a financial reward to providers who were prescribing large amounts of the Fentanyl Spray and to incentivize those providers to continue to prescribe the Fentanyl Spray in the future.

59. Senior officials and managers of the Pharmaceutical Company, including A.B., J.P. and J.R., regularly informed Company sales representatives that they should expect a "return on the investment" given to doctors who were part of the Speaker Program and that they should inform these doctors that they would not obtain any future speaking programs if they did not prescribe more of the Fentanyl Spray.

60. Defendant JERROLD ROSENBERG began prescribing the Fentanyl Spray to his patients in April 2012 and began receiving payments from the Pharmaceutical Company for speaking events shortly thereafter. ROSENBERG was far and away the biggest prescriber of the Fentanyl Spray in Rhode Island and one of the top prescribers of the Fentanyl Spray in the United States. ROSENBERG prescribed the Fentanyl Spray to patients suffering from a wide variety of ailments, including many patients who were not suffering from breakthrough pain due to cancer.

61. From July 2012 through July 2015, the Pharmaceutical Company paid ROSENBERG approximately \$180,000 for conducting approximately 91 speaking programs concerning the drug the Fentanyl Spray. Many of these were sham programs in which the only attendees were members of ROSENBERG's family and the Pharmaceutical Company sales representative. In other programs, the same attendees, doctors who were friends and/or colleagues of ROSENBERG, attended dinner programs over and over again.

62. For numerous of the sham speaking programs, there were no attendees, other than ROSENBERG, who were authorized to prescribe medications.

63. For numerous of the sham speaking programs conducted by ROSENBERG, the attendees were ROSENBERG's wife and other relatives of ROSENBERG. ROSENBERG regularly forged the signatures of other individuals on the sign-in-sheets to falsely make it appear that medical professionals attended the programs. In addition, ROSENBERG regularly ordered extra meals, to make it appear on the restaurant receipt that other persons attended the event.

64. In addition to providing payments to ROSENBERG in exchange for sham speaking programs, Pharmaceutical Company officials further induced ROSENBERG to prescribe the Fentanyl Spray by hiring his son A.R. as a sales representative, assigning A.R. to be ROSENBERG's sales representative and by paying A.R. substantial compensation based, in large part, on the amount of the Fentanyl Spray prescribed by ROSENBERG.

65. In order to generate greater income to the Pharmaceutical Company, Pharmaceutical Company officials and sales representatives encouraged providers, including ROSENBERG, to prescribe the Fentanyl Spray at higher dosages. Sales representatives assigned to ROSENBERG, including A.R. and N.L., regularly informed ROSENBERG that the Pharmaceutical Company wanted him to prescribe the Fentanyl Spray to more patients and at higher doses. In exchange for payments to him and his son, ROSENBERG prescribed greater amounts of the Fentanyl Spray at higher doses.

66. In order to increase his remuneration from the Pharmaceutical Company, defendant ROSENBERG actively sought out more and more speaking programs from the Pharmaceutical Company.

67. ROSENBERG was regularly informed by Pharmaceutical Company Sales Representatives N.L. and J.C. that he needed to prescribe the Fentanyl Spray to more patients if he wanted to receive more paid speaking programs. ROSENBERG agreed to do so.

68. In order to obtain a greater number of speaking programs and remuneration from the Pharmaceutical Company, ROSENBERG regularly provided false and fraudulent information to Plan Sponsors, PBM's and Insurance Companies concerning patients' diagnoses and the effectiveness of other medications. By providing false diagnoses to insurance companies, ROSENBERG was able to successfully prescribe more and more of the Fentanyl Spray which, in turn, generated more and more profits to the Pharmaceutical Company, more and more speaking fees to ROSENBERG and more commissions to A.R.

69. The use of the Fentanyl Spray did not alleviate the pain experienced by some of ROSENBERG's patients. When these patients complained of this fact to ROSENBERG, he refused their requests to switch them from the Fentanyl Spray to another pain medication, telling them that if they wanted another drug, they would need to find another doctor.

70. Certain of ROSENBERG's patients experienced debilitating side effects as a result of their use of the Fentanyl Spray. When these patients informed ROSENBERG of how much they were suffering from the Fentanyl Spray and requested to be switched from the Fentanyl Spray to another pain medication, ROSENBERG refused to do so.

71. When R. S.D., a physician assistant who worked for ROSENBERG, became concerned about ROSENBERG's prescribing of the Fentanyl Spray to many patients and discovered that numerous of these patients did not, in fact, have cancer, R. S.D. began weaning patients off of the Fentanyl Spray who had previously been prescribed the Fentanyl Spray by ROSENBERG. ROSENBERG then prohibited R. S.D. from treating patients who received the Fentanyl Spray.

72. In exchange for speaker fees and commission payments to his son, ROSENBERG wrote more prescriptions for the Fentanyl Spray, including prescriptions that were paid for by federal programs.

Acts In Furtherance Of Conspiracy

In furtherance of the conspiracy and to accomplish its objectives and purposes, the following acts, among others, were committed by one or more of the co-conspirators in the District of Rhode Island and elsewhere:

73. On or about March 30, 2012, ROSENBERG traveled to Phoenix, Arizona where he met and played golf with Pharmaceutical Company officials and had dinner with former Pharmaceutical Company Chief Executive Officer M.B.

74. On or about April 3, 2012, ROSENBERG sent Pharmaceutical Company Chief Executive Officer M.B. an e-mail in which he wrote that his son A.R. would like to be a sales representative for the Pharmaceutical Company.

75. On or about June 1, 2012, the Pharmaceutical Company offered A.R. the position of Specialty Sales Professional and assigned him to be the sales representative for his father ROSENBERG.

76. On or about June 26, 2012, ROSENBERG entered into a Speaking Agreement with the Pharmaceutical Company in which he agreed to give presentations concerning the Fentanyl Spray in exchange for remuneration.

77. On or about July 23, 2012, ROSENBERG caused to be submitted to Silverscript a Prior Authorization request for the Fentanyl Spray that falsely represented that patient P.F. was experiencing pain due to basal cell carcinoma.

78. On or about December 19, 2012, ROSENBERG sent a Letter of Medical Necessity to United Healthcare for the Fentanyl Spray in which he falsely wrote that patient D.M. had breast cancer.

79. On or about March 29, 2013, ROSENBERG sent an e-mail to his son A.R. asking him to arrange for him to receive more speaking programs "before [the Pharmaceutical Company] pulls funding."

80. On or about April 2, 2013, Regional Sales Manager J.P. sent an e-mail to A.R. and other Pharmaceutical Company sales representatives instructing them to tell their doctors that they "will have x programs from x dollars in order to hold them accountable and motivate them to write more scripts" and that "you are clearly missing the value of these programs if you haven't thrown it in your doctor's face."

81. On or about May 22, 2013, ROSENBERG received and deposited check number 011177 from the Pharmaceutical Company in the amount of \$3,200.

82. On or about June 26, 2013, ROSENBERG caused to be submitted to Catamaran a Prior Authorization request for the Fentanyl Spray that falsely represented that patient D.N. was suffering from breakthrough cancer pain.

83. On or about September 12, 2013, ROSENBERG met with some individuals at a restaurant in Providence, Rhode Island where he was paid to speak about the Fentanyl Spray. The attendees included M.M., an orthopedist from Cranston, Rhode Island, who was a colleague of ROSENBERG and who attended numerous of ROSENBERG's purported speaking engagements. ROSENBERG forged the signature of R. S.D. on the sign-in-sheet.

84. On or about October 3, 2013, ROSENBERG met with Pharmaceutical Company sales representative N.L. at a restaurant in East Greenwich, Rhode Island. ROSENBERG forged the signature of M.M. on the sign-in sheet to make it falsely appear that another person was there. Despite the absence of any other medical personnel and failure to provide any type of presentation concerning the Fentanyl Spray, ROSENBERG was paid \$1,600 by the Pharmaceutical Company.

85. On or about October 21, 2013, ROSENBERG received check number 000180, issued by the Pharmaceutical Company, in the amount of \$3,200.

86. On or about November 14, 2013, Pharmaceutical Company District Manager J.R. emailed a team of sales representatives, including ROSENBERG's representative N.L.: "DON'T BE ONE OF THOSE REPS! Almost all of you have speakers, use that to your advantage and repeatedly inform them of one simple guideline for them to follow as [Pharmaceutical Company] speakers. NO SCRIPTS, NO PROGRAMS."

87. On or about March 24, 2014, ROSENBERG caused to be sent by facsimile to the Pharmaceutical Company a Prior Authorization Request form that falsely represented that patient R.S. had lung cancer.

88. On or about May 5, 2014, ROSENBERG received check number 002933, issued by the Pharmaceutical Company, in the amount of \$4,400.

All in violation of 18 U.S.C. § 371.

COUNTS 15-19
(Receipt of Kickbacks)

89. The Grand Jury realleges and incorporates by reference paragraphs 1-88 above as if fully set forth herein.

90. In exchange for prescribing the Fentanyl Spray to new patients and increasing the dosage of the Fentanyl Spray prescribed to existing patients, defendant ROSENBERG was paid substantial compensation by the Pharmaceutical Company.

91. The Pharmaceutical Company funneled substantial sums of money to ROSENBERG by paying him for purported speaking programs ROSENBERG provided to other health care professionals concerning the Fentanyl Spray. This money was paid to ROSENBERG to reward him for prescribing the Fentanyl Spray to his patients and to incentivize him to continue to prescribe the Fentanyl Spray to new patients and to increase the dosages of the Fentanyl Spray he prescribed to existing patients.

92. Defendant ROSENBERG actively sought more and more money from the Pharmaceutical Company as he regularly informed the Pharmaceutical Company sales representatives that he "needed" more speaking programs.

93. The Pharmaceutical Company sales representatives regularly informed ROSENBERG that he needed to write more prescriptions for the Fentanyl Spray and to increase the dosages for patients already taking the Fentanyl Spray if he was to obtain more speaking programs. ROSENBERG agreed to do so.

94. Many of the purported speaking programs conducted by ROSENBERG were sham programs in which no other medical professionals permitted to prescribe the Fentanyl Spray were even present. In numerous of these purported speaking programs, the only attendees were the Pharmaceutical Company sales representative, ROSENBERG, and members of ROSENBERG's family.

95. In order to make it appear that he was conducting legitimate speaking programs concerning the Fentanyl Spray, ROSENBERG regularly forged the signatures of individuals on sign-in sheets, including the signatures of R. S.D., physician M.M. and members of ROSENBERG's office staff. The Pharmaceutical Company sales representatives, including A.R. and N.L., then knowingly submitted the false and fraudulent sign-in sheets to the Pharmaceutical Company and to the third-party companies hired by the Pharmaceutical Company to manage the Speaking Program.

96. On or about the dates listed below, in the District of Rhode Island and elsewhere, defendant JERROLD ROSENBERG did knowingly and willfully solicit and

receive the remuneration listed below, directly and indirectly, overtly and covertly, in return for purchasing and ordering, and arranging for the purchase and order of goods, services and items, that is, prescriptions for the Fentanyl Spray, for which payment was made in whole or in part by a Federal health care program, namely Medicare:

Count	Date Payment Received by Rosenberg	Payment Amount	Date & Place of Purported Speaking Program
15	08/13/2013	\$1,600.00	07/22/2013 at Capital Grille Restaurant in Providence, RI
16	09/13/2013	\$1,600.00	9/4/2013 at Capital Grille Restaurant in Providence, RI
17	10/4/2013	\$2,500.00	10/2/2013 at 1149 Restaurant in East Greenwich, RI
18	10/09/2013	\$1,600.00	10/3/2013 at 1149 Restaurant Restaurant in East Greenwich, RI
19	01/30/2014	\$1,600.00	1/8/2014 at Besos Tea House in East Greenwich, RI

Each in violation of 42 U.S.C. § 1320a-7b(b).

A TRUE BILL:

REDACTED

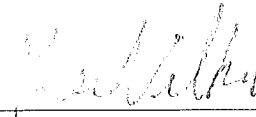
PETER F. NERONHA
UNITED STATES ATTORNEY



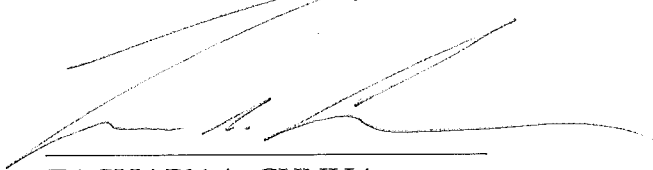
SANDRA HEBERT
Deputy Criminal Chief
Assistant U.S. Attorney

2/1/17

DATE



LEE H. VILKER
Assistant U.S. Attorney



ZACHARY A. CUNHA
Assistant U.S. Attorney